

Bulk Drug Substances Nominated for Use in Compounding Under Section 503A of the Federal Food, Drug, and Cosmetic Act

503A Category 1 – Bulk Drug Substances Under Evaluation

- 7 Keto Dehydroepiandrosterone
- Acetyl L Carnitine/Acetyl-L-carnitine hydrochloride
- Acetyl-D-Glucosamine
- Alanyl-L-Glutamine
- Aloe Vera/ Aloe Vera 200:1 Freeze Dried
- Alpha Lipoic Acid
- Ammonium Tetrathiomolybdate
- Artemisia/Artemisinin
- Astragalus Extract 10:1
- Beta Glucan (1,3/1,4-D)
- Boswellia
- Brilliant Blue
- Bromelain
- Cantharidin
- Cesium Chloride
- Cetyl Myristoleate
- Choline Chloride
- Chondroitin Sulfate
- Chrysin
- Curcumin
- Dehydroepiandrosterone
- Deoxy-D-Glucose
- Dichloroacetate
- Diindolylmethane
- Dimercapto-1-propanesulfonic acid (DMPS)
- Diphenylcyclopropenone (DPCP)
- EGCg
- Ferric Subsulfate
- Glutaraldehyde
- Glutathione
- Glycoaminoglycans
- Glycolic Acid
- Glycyrrhizin
- Glycyrrhizin
- Kojic Acid
- L-Citrulline
- Methylcobalamin
- Methylsulfonylmethane (MSM)
- Nettle leaf (*Urtica dioica* subsp. *dioica* leaf)
- Nicotinamide Adenine Dinucleotide (NAD)
- Nicotinamide Adenine Dinucleotide Disodium Reduced (NADH)
- Ornithine Hydrochloride
- Oxitriptan
- Phosphatidylserine
- Piracetam
- Pregnenolone
- Pyridoxal 5-Phosphate Monohydrate
- Pyruvic Acid
- Quercetin/Quercetin Dihydrate
- Quinacrine Hydrochloride (except for intrauterine administration)
- Resveratrol
- Ribose (D)
- Rubidium Chloride
- Silver Protein Mild
- Squaric Acid Dibutyl Ester (aka dibutyl squarate)
- Tea tree oil (*Melaleuca alternifolia* leaf oil)
- Thymol Iodide
- Tranilast
- Trichloroacetic Acid
- Ubiquinol 30% Powder
- Vanadium
- Vasoactive Intestinal Peptide

503A Category 2: Bulk Drug Substances that Raise Significant Safety Risks

- Domperidone
- Germanium Sesquioxide
- Quinacrine Hydrochloride for intrauterine administration

503A Category 3: Bulk Drug Substances Nominated Without Adequate Support

- Acetanilide
- Acetone Sodium Bisulfite
- Acetyl Hexapeptide-3
- Acidophilus Lactobacillus
- Adenosine-5-triphosphate disodium salt
- Alcloxa
- Aldioxa
- Aldosterone
- Alfalfa
- Alfalfa leaves
- Aliphatic Polyesters
- Almadrate sulfate
- Aloin
- Alpha Ketoglutaric acid
- Alumina Powder, hydrated
- Aluminum phosphate
- Aminacrine Hydrochloride
- Ammonium Alginate
- Ammonium bromide
- Ammonium hydroxide
- Anise seed
- Argentyn
- Aromatic powder
- Asafetida
- Asclepias tuberosa
- Asefetida Tincture
- Asparagus
- Aspergillus oryza enzymes
- Barosma
- Beechwood creosote
- Bean
- Betamechlomathasone
- Beta-Nicotinamide Adenine Dinucleotide Disodium Salt Trihydrate
- Bichloroacetic Acid
- Bi peptide Biocosmetic
- Bronopol
- Buffer Solution, pH Buffer Acid
- Calcium Alginate
- Calcium Folinate
- Calcium Glycinate
- Capsules, Empty Gelatin Vegetable
- Carbazochrome
- Carbimazole
- Cedarwood Essential Oil
- Ceratonia
- Ceresin
- Cetrimide
- Chlorhexidine Diacetate Hydrate
- Choline bitartrate
- Choline magnesium trisalicylate
- Chromium glycinate
- Coenzyme Q10
- Coenzyme Q50
- Colophony
- Copper
- Copper Bisglycinate
- Copper Hydrosol
- Creatine, Monohydrate
- Cucumber Melon Fragrance
- Decyl Oleate
- Decylmethylsulfoxide
- Diaminopyridine (3,4-)
- Dichloroacetic acid
- Difluoroethane
- Dimethyl Ether (aka Methoxymethane)
- Dimethyl Ketone
- Dimethyl Phthalate
- Dimethylacetamide
- Dimethylaminoethanol Bitartrate
- Dimethylaminoethanol Complex
- Dimethylglycine Hydrochloride
- Dinitrochlorobenzene
- Dipropylene Glycol
- Disodium Phosphate
- DL-Phenylalanine
- Dodecyl Gallate
- Edetate tetrasodium tetrahydrate
- Ethyl Lactate
- Ethylene Vinyl Acetate
- Gamma Aminobutyric Acid
- GHRP-2
- GHRP-6
- Ginger root powder
- Ginkgo Biloba Standardized Extract
- Gluconic acid calcium salt
- Glycerol Formal

- Glyceryl Palmitostearate
- Glycofurool
- Glydiazinamide
- Grape seed oil
- Heart-leaf nettle leaf (Urtica chamaedryoides leaf)
- Hectorite
- Heptafluoropropane
- Hexetidine
- Hyaluronic Acid Sodium Salt
- Hydrazine sulfate
- Hydroxyethylpiperazine Ethane Sulfonic Acid
- Hydroxymethylmethyl Cellulose
- Indigo Carmine
- Indole-3-carbinol
- Inositol Hexanicotinate
- Iron Glycinate Chelate
- Isopropyl Isostearate
- Karaya Gum
- Ketoifen Fumarate
- Lavender Oil
- L-Carnosine
- Lecithin Soya Granular
- Lecithin Organogel
- Levulose
- L-Histidine Monohydrochloride, Monohydrate
- Linoleic Acid
- L-Ornithin Hydrochloride
- Loxasperse
- L-Triiodothyronine Sodium
- Magnesium ascorbate
- Magnesium bisglycinate
- Magnesium bisglycinate dihydrate
- Magnesium glycinate
- Malt
- Malt soup extract
- Maltodextrin
- Manganese Bisglycinate
- Manganese citrate
- MBK
- m-cresol
- Medium Cream
- Melatonin
- Menfegol
- Meralein sodium
- Merbromin
- Mercufenol chloride
- Mercuric chloride
- Mercuric oxide
- Mercuric salicylate
- Mercuric sulfide
- Mercury
- Mercury oleate
- Mercury sulfide
- Methapyrilene fumarate
- Methoxyphenamine Hydrochloride
- Methoxypolyoxyethyleneglycol 350 laurate
- Methyl nicotinate
- Methylpyrilene Hydrochloride
- Milk and molasses
- milk solids, dried
- Minerals
- Molasses
- Molybdenum Glycinate
- Monosodium L-Aspartate
- Mullein
- Mustard oil (alltishthiocyanate)
- Mycozyme
- Myrrh gum tincture
- Myrrh tincture
- Natural estrogenic hormone
- Neohesperidine Dihydrochalcone
- Nickel-pectin
- Non-Fat Dry Milk
- Nonylphenoxy poly (ethyleneoxy) ethanol iodine
- Nonylphenoxy poly nonoxynol 9
- Noscapine Hydrochloride
- Nutmeg oil
- Nux vomica extract
- Obtundia
- Octyl Gallate
- Octyl triazole
- Oil of erigeron

- Organic vegetables
- Orthophosphoric acid
- Ox bile
- Ox bile extract
- Oxyquinoline
- Padimate a
- Pambron
- Pantothenic acid
- Papaya enzymes
- Papaya, natural
- Para-chloromercuriphenol
- Parethoxycaine Hydrochloride
- Parsley
- Passion flower extract
- Patchouli Essential Oil
- Pennyroyal Oil
- Pentylenetetrazole
- Peppermint Oil and Sage Oil
- Pepsin
- Peruvian balsam (*Myroxylon balsamum* var. *pereirae* balsam)
- Phenacaine Hydrochloride
- Phenindamine Tartrate
- Phenolate sodium
- Phenolphthalein
- Phenoxyacetic acid
- Phenyl salicylate (Salol)
- Phenyl salicylate
- Phenylmercuric Borate
- Phenyltoloxamine dihydrogen citrate
- Phenyltoloxamine Hydrochloride
- Phosphate fluoride
- Phosphorated carbohydrate
- Phosphorus
- Phytolacca
- Picrotoxin
- Pimobendan
- Pine tar
- Piperocaine Hydrochloride
- Pipsissewa
- Piracetam dihydrogen citrate
- Piscidia erythrina
- Plantago ovata husks
- Poloxamer-iodine complex
- Poly (DL-Lactic Acid)
- Poly(methyl vinyl ether/maleic anhydride)
- Polydimethylsiloxane and poloxamer
- Polyols, liquid
- Polyoxyethylene laurate
- Potash Lye
- Potassium chlorate
- Potassium ferrocyanide
- Potassium salicylate
- Povidone-vinylacetate copolymers
- Pracasil Plus
- Prolase
- Prune concentrate dehydrate
- Prune powder
- Psyllium
- Psyllium hydrophilic mucilloid
- P-T-butyl-m-cresol
- Pyrrolidone
- Pyruvic aldehyde
- Pyruvic Aldehyde 40% Aqueous Solution
- Quinine
- Racephpedrine Hydrochloride
- Raffinose
- Red petrolatum
- Reosote
- Rhubarb fluid extract
- Rhubarb, Chinese
- Rice pollishings
- Romohydrate
- Sabadilla, alkaloids
- Sage oil
- Salicyl alcohol
- Sanguinaria extract
- Saponite
- Saw palmetto
- Scopolamine aminoxide Hydrobromide
- Sea mineral
- Senecio aureus
- Senna syrup
- Serotonin Hydrochloride

- Sesame Seed
- Shark liver oil
- Shea Butter, Organic
- Short Chain Fatty Acid
- Silver (see also argentyn)
- Silver, colloidal
- Simplgel 30
- Sodium 3, 4-dimethylphenyl-glyoxylate
- Sodium acetylsalicylate
- Sodium aluminum chlorohydroxy lactate
- Sodium aspartate
- Sodium biphosphate
- Sodium bisulfate
- Sodium borate monohydrate
- Sodium caseinate
- Sodium diacetate
- Sodium dichromate
- Sodium dihydrogen phosphate monohydrate
- Sodium hyaluronate
- Sodium nitrate
- Sodium octanoate
- Sodium oleate
- Sodium para-amino benzoate
- Sodium perborate
- Sodium perborate monohydrate
- Sodium phosphate
- Sodium potassium tartrate
- Sols, secondary
- Soy meal
- Soybean protein
- Splenda
- Squill preparations
- Stannous pyrophosphate and zinc citrate
- Stevia Powder Extract
- Strawberry
- Strychnine
- Sucros
- Sugars
- Sulferated oils of turpentine
- Sulfolbutylether B-Cyclodextrin
- Supposibase-F
- T3 Sodium Dilution
- Tannic acid glycerite
- Taraxacum officinale
- Tartrate
- Teaberry Oil
- Tetrafluoroethane
- Tetrahydrochloride
- Thaumatin
- Thenyldiamine Hydrochloride
- Theobromine Sodium Salicylate
- Theophylline calcium salicylate
- Thioctic
- Thiocyanatoacetate
- Thonzylamine Hydrochloride
- Threonine
- Thylene blue
- Tolindate
- Toltrazuril
- Tolu preparations
- Tommygel
- Tricalcium phosphate
- Tricaprylin
- Triethanolamine
- Triglycerides
- Trillium
- Triolein
- Triple dye
- Triticum
- Turpantine Oil
- Turpantine, Venice
- Uinolinium bromide
- Ulose
- Uva ursi, extract of
- Valic acid
- Vitamin A acetate
- Vitromersol
- Water and additives
- Wheat germ
- Wheat germ (triticum aestivum/vulgare extract)
- White ointment
- Woodruff
- Yeast
- Yeast cell derivative
- Yellow mercuric oxide

- Zinc caprylate
- Zinc citrate
- Zinc phenol sulfonate
- Zinc picolinate
- Zinc propionate
- Zinc sulfide
- Zirconium oxide
- Zyloxin